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09/977,059	10/11/2001	Prasad V.V.S.V. Mancham	25352-0029	1824

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HELLER EHRMAN WHITE & MCAULIFFE LLP  
275 MIDDLEFIELD ROAD  
MENLO PARK, CA 94025-3506

EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/977,059

Applicant(s)

MANCHEM ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-29 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-29 and 31-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is a response to Applicant's amendment and response to the previous Office Action (mailed March 23, 2004), filed September 23, 2004 wherein the instant specification has been amended as to page 16, lines 8-16, regarding to the incorporation of US patent as parallel to WO patents; claims 21-29 and 31-36 have been amended; claim 30 is cancelled. claims 1-20 are cancelled previously.

Currently, claims 21-29 and 31-36 are pending in this application.

Claims 21-29 and 31-36 are examined on the merits herein.

As indicated in the previous Office Action, the terminal disclaimer filed on December 17, 2003, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. 6,458,998 has been reviewed and is accepted. The terminal disclaimer has been recorded. Therefore, the obviousness-type double patenting rejection of record stated in the previous Office Action dated is withdrawn.

Applicant's amendment that amends the specification at page 16 lines 8-16, filed September 23, 2004, with respect to the objection to the Specification of record stated in the Office Action dated March 23, 2004 have been fully considered and are found persuasive. Therefore, this objection is withdrawn.

Applicant's amendment and remarks filed September 23, 2004 with respect to the rejection of claims 21-22 and 30-36 made under 35 U.S.C. 112 first paragraph for containing new subject matter, i.e., "those compounds having Formula I in particular when Y is now newly defined in claim 21 and those particular compounds (subgenus and species) in claims 22", of record stated in the Office Action dated March 23, 2004 have been fully considered and found persuasive to remove the rejection since the compounds themselves when Y is now newly defined in claim 21 (subgenus) and those particular compounds (subgenus) in claims 22 taught in the US patent 6,458,998 which is incorporated herein by reference in the specification. Moreover, with respect to written description, the specification as filed originally discloses that insulin receptor-activating compound in general are useful in the claimed method herein, and therefore provides support for the method of treating a metabolic disorder in a person induced by an HIV protease inhibitor, as Applicant asserts.

Therefore, the said rejection is withdrawn.

Applicant's amendment and remarks filed September 23, 2004 with respect to the rejection of claims 21-36 made under 35 U.S.C. 112 first paragraph for lack of scope of enablement of record stated in the Office Action dated March 23, 2004 has been fully considered and is found persuasive to remove, since the particular metabolic disorders have been recited. Moreover, the recitation, "an HIV protease inhibitor", is reasonably interpreted as those known HIV protease inhibitors as of the instant filing date as described in "Background of the Invention" at page 1-2 of the specification. The

recitation, "an additional form of treatment for insulin resistance, hyperglycemia ...", is reasonably interpreted as insulin or insulin analog, as recited in claims 33-36. Insulin or insulin analog is well-known in the art for the treatment for insulin resistance, hyperglycemia .... Therefore, the said rejection is withdrawn.

Applicant's remarks filed September 23, 2004 with respect to the rejection of claims 32 and 34-36 made under 35 U.S.C. 112 second paragraph for the use of the indefinite recitations, i.e., "insulin analog" and " less than the amount of the additional form of treatment" of record stated in the Office Action dated March 23, 2004 have been fully considered and found persuasive to remove the rejection. Therefore, the said rejection is withdrawn.

The following is the new ground(s) of rejection(s).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-29 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kauvar et al. (WO 98/32017, PTO-892).

Kauvar et al. discloses that the compounds of formula (1) or formula (2) when the linker is  $\text{-NHCONH-}$ , (see abstract and page 7, 21), are insulin receptor-activating compounds and thus are useful a method for treating the particular metabolic disorders such as insulin resistant and diabetes in general. The compounds of Kauvar et al. are seen to broadly cover and encompass the instant compounds of formula (I), for example, compounds TER3935 (2A, 2B) and TER17005 at page 24-25, are seen to be substantially close and similar to the instant compound. See also claims 14-25.

Kauvar et al. does not expressly disclose the employment of the particular insulin receptor-activating compounds, in a method of treating insulin resistant and/or diabetes in a person induced by treatment with an HIV protease inhibitor. Kauvar et al. does not also expressly disclose the particular compounds in claims 22 and 29 herein. Kauvar et al. does not also expressly disclose further employment of insulin or insulin analog in the treatment therein.

However, as Applicant acknowledges and admits in the specification and remarks filed September 23, 2004, regarding as prior art that insulin or insulin analog, is well-known in the art for the treatment for insulin resistant and/or diabetes.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular insulin receptor-activating compounds of Kauvar et al. or the particular compounds herein, in a method of treating insulin resistant and/or diabetes in a person induced by treatment with an HIV protease inhibitor.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular insulin receptor-activating compounds of Kauvar et al. or the particular compounds herein, in a method of treating insulin resistant and/or diabetes in a person induced by treatment with an HIV protease inhibitor, since the compounds of Kauvar et al. which broadly covered and encompassed the instant compounds of formula (I), and/or substantially close and similar to the instant compounds, are known insulin receptor-activating compounds and are thus useful a method for treating the particular metabolic disorders such as insulin resistant and/or diabetes in general, according to Kauvar et al.

Hence, the patient population having insulin resistant and/or diabetes in general in Kauvar et al. is deemed to overlap or coincide with the patient population also suffering insulin resistant and/or diabetes induced by treatment with an HIV protease inhibitor.

Therefore, one of ordinary skill in the art would have reasonably expected that the particular compounds of Kauvar et al. would have beneficial therapeutic effects and usefulness in a method of treating insulin resistant and/or diabetes in a person induced by treatment with an HIV protease inhibitor.

Additionally, one of ordinary skill in the art would have reasonably expected that the instant particular compounds, would have same or substantially similar beneficial therapeutic effects and usefulness as the compounds of Kauvar et al. in methods of treating insulin resistant and/or diabetes, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at

693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214, and If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species, In fact, similar properties may normally be presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904, as noted in MPEP 2144.

Claims 21-29 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (WO 98/50347, PTO-892).

Kenyon et al. discloses that the Compound A (see page 2) or compounds having formula at page 5-11, Table 1 at page 19-33 when X linker is –NHCONH– such as Compound 5 and 159, are useful a method for treating HIV infection in general (see abstract). The compounds of Kenyon et al. are seen to broadly cover and encompass the instant compounds of formula (I), or to be substantially close and similar to the instant compound. See also claims 1-19.

Kenyon et al. does not expressly disclose the employment of the particular compounds therein, in a method of treating insulin resistant and/or diabetes in a person induced by treatment with an HIV protease inhibitor. Kenyon et al. does not also expressly disclose the particular compounds in claims 22 and 29 herein. Kenyon et al. does not also expressly disclose further employment of insulin or insulin analog in the treatment therein.



However, as Applicant acknowledges and admits in the specification and remarks filed September 23, 2004, regarding as prior art that insulin or insulin analog, is well-known in the art for the treatment for insulin resistant and/or diabetes.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular compounds of Kenyon et al. or the particular compounds herein, in a method of treating insulin resistant and/or diabetes in a person induced by treatment with an HIV protease inhibitor.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular compounds of Kenyon et al. or the particular compounds herein, in a method of treating insulin resistant and/or diabetes in a person induced by treatment with an HIV protease inhibitor, since the compounds of Kenyon et al. which broadly covered and encompassed the instant compounds of formula (I), and/or substantially close and similar to the instant compounds, are known to be useful a method a method for treating HIV infection in general, according to Kenyon et al.

Hence, the patient population having HIV in general in Kenyon et al. is deemed to overlap or coincide with the patient population also suffering insulin resistant and/or diabetes induced by treatment with an HIV protease inhibitor.

Therefore, one of ordinary skill in the art would have reasonably expected that the particular compounds of Kenyon et al. would have beneficial therapeutic effects and usefulness in a method of treating insulin resistant and/or diabetes in a person induced by treatment with an HIV protease inhibitor.

Art Unit: 1617

Additionally, one of ordinary skill in the art would have reasonably expected that the instant particular compounds, would have same or substantially similar beneficial therapeutic effects and usefulness as the compounds of Kenyon et al. in methods of treating HIV in general, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214, and If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. In fact, similar properties may normally be presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904, as noted in MPEP 2144.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.  
Primary Examiner, AU 1617  
December 7, 2004